AMENDED IN ASSEMBLY APRIL 13, 2011

AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 1277

Introduced by Assembly Members Hill and Perea

February 18, 2011

An act to amend Sections 111550 and ~~111630~~ *111635* of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1277, as amended, Hill. Sherman Food, Drug, and Cosmetic Law.

~~(1) The~~

The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices, and is administered by the State Department of Public Health. The law prohibits the sale, delivery, or giving away of any new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under specified provisions of the federal Food, Drug, and Cosmetic Act, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act.

~~(2) The~~

The Sherman Food, Drug, and Cosmetic Law requires the department to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

This bill would revise the ~~above described~~ *above-described* prohibition~~, as specified, and require the department to waive the fee for the issuance and renew of a license for a person who has paid the most recent annual fees required pursuant to the federal act~~ *to also apply to a new biologic product for which a license has been issued under federal law*.

Existing law also requires the department to inspect the place of business of each licensed person once every 2 years, unless the United States Food and Drug Administration inspected the place of business within the previous 2 years.

This bill would require inspections once every 4 years, unless the United States Food and Drug Administration inspected the place of business within the previous 4 years.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 111550 of the Health and Safety Code is amended to read:

111550. No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is ~~a~~ *one of the following:*

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. ~~355); it is a~~ *355).*

(2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. ~~262), or it is a~~ *262).*

(3) A new device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360) ~~and~~ *or* for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has

not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug or in the case of a new device, a full statement of its composition, properties, and construction and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

(c) It is the intent of the Legislature to preclude the department from requiring a person who intends to sell, deliver, or give away any new drug or device that meets the federal requirements described in subdivision (a) to also obtain an approval pursuant to subdivision (b), except to the extent that the department requires documentation that the federal requirements are met.

~~SEC. 2. Section 111630 of the Health and Safety Code is amended to read:~~

~~111630. (a) The department shall by regulation establish the application form and set the fee for licensure and renewal of a license. The penalty for failure to apply for renewal of a license within 30 days after its expiration is ten dollars ($10) and shall be added to the renewal fee and be paid by the applicant before the renewal license may be issued. All moneys collected as fees shall be expended when appropriated by the Legislature in the carrying out of this part and the regulations adopted pursuant to this part.~~

~~(b) Notwithstanding subdivision (a), the department shall waive the fee for the issuance and renew of a license for a person licensed~~

~~pursuant to this section who has paid the most recent annual fees required pursuant to the federal act.~~

~~(c) A person licensed pursuant to this section shall immediately notify the department of any change in the information reported in the license application.~~

SEC. 2. Section 111635 of the Health and Safety Code is amended to read:

111635. (a) Prior to issuing a license required by Section 111615, the department shall inspect each place of business.

(b) The department shall subsequently inspect the place of business of each person licensed under Section 111615 once every ~~two~~ *four* years. The department shall conduct these inspections to determine ownership, adequacy of facilities, and personnel qualifications. Where the United States Food and Drug Administration has conducted an inspection of the place of business within the previous ~~two~~ *four* years, the department shall use the information contained in the written documentation pertaining to that inspection rather than conducting its own inspection pursuant to this subdivision. The department may, if necessary, inspect to obtain information not included or not sufficiently clear in the United States Food and Drug Administration written documentation pertaining to the inspection and needed to ~~determine ownership, adequacy of facilities, personnel qualifications, and compliance with this part~~ *protect the health and safety of the public*.

(c) The department may, in lieu of all or part of any inspection required under this section, use information from audits conducted pursuant to the provisions of the International Standards Organization (ISO) 9000 series or European (EN) 46000 series quality system standards, or other information identified by the department by regulation.

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